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Oversight on the borderline: quality improvement and pragmatic research

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Abstract

Pragmatic research that compares interventions to improve the organization and delivery of health care may overlap, in both goals and methods, with quality improvement (QI) activities. When activities have attributes of both research and QI, confusion often arises about what ethical oversight is, or should be, required. For routine QI, in which the delivery of health care is modified in minor ways that create only minimal risks, oversight by local clinical or

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administrative leaders utilizing institutional policies may be sufficient. However, additional consideration should be given to activities that go beyond routine, local QI to first determine whether such non-routine activities constitute research or QI and, in either case, to ensure that independent oversight will occur. This should promote rigor, transparency, and protection of patients' and clinicians' rights, well-being, and privacy in all such activities. Specifically, we recommend: 1. Health care organizations should have systematic policies and processes for designating activities as routine QI, non-routine QI, or QI research, and determining what oversight each will receive. 2. Health care organizations should have formal and explicit oversight processes for non-routine QI activities that may include input from institutional QI experts, health services researchers, administrators, clinicians, patient representatives, and those experienced in the ethics review of health care activities. 3. QI research requires review by an IRB; for such review to be effective, IRBs should develop particular expertise in assessing QI research. 4. Stakeholders should be included in the review of non-routine QI and QI-related research proposals. Only by doing so will we optimally leverage both pragmatic research on health care delivery and local implementation through QI as complementary activities for improving health.

Keywords

Quality Improvement; Research; Health Care Operations; Pragmatic Clinical Trials; Ethics; Stakeholder Engagement; Patient Engagement

Introduction

Patients and their healthcare providers face a need for better information on which interventions are most effective in routine practice settings *and* for more rapid and reliable implementation of those interventions once identified. The former is the realm of pragmatic (or practical) research (creation of new generalizable knowledge about clinical alternatives), while the latter is the purview of quality improvement (QI). Pragmatic clinical research compares therapeutic agents, procedures, behavioral interventions, and diagnostic strategies in normal practice settings. Pragmatic research trials are also used to evaluate systemic interventions to improve the organization and delivery of health care. These and other research activities can overlap, in both goals and methods, with QI. When activities have attributes of both research and QI, healthcare institutions face uncertainty about what oversight is, or should be, provided and especially about the applicability of the current regulatory framework of human subjects protection. Moreover, while much attention has been focused on patient engagement in both research and QI activities,[1] we know little about what patients and other stakeholders believe are reasonable approaches to activities that may have attributes of both.

The language that is typically used to differentiate types of 'learning activities', including QI and research, is imprecise. Although federal regulations (45 CFR 46) describe research as an activity intended to create generalizable knowledge, many have noted the limitations of this rather simplistic criterion.[2–4] QI, in turn, has been defined as "... systematic, data-guided activities designed to bring about *immediate improvements* in health care delivery in particular settings."[5] Here, for the purpose of discussing ethical oversight, we will categorize

activities as “routine QI,” “non-routine QI,” and “QI research.” “Routine QI” consists of activities that aim to more reliably deliver intended care processes in a particular health care organization. They include low-risk (from a patient's or clinician's perspective) activities to improve care locally by making small changes in rapid cycles (i.e. Plan-Do-Study-Act [PDSA] cycles),[6] implementing successful interventions immediately, and testing additional changes until pre-specified goals are met. An example would be testing whether use of a checklist for elements of already required screening (e.g., for smoking status) increases reliability of that process. The Centers for Medicare and Medicaid Services (CMS) and accrediting bodies such as The Joint Commission mandate that healthcare organizations undertake routine QI activities.[7,8] While QI may result in new information that might be of interest outside the institution, *routine QI* activities are not designed to support causal inference or to be widely generalizable to other settings, according to accepted scientific standards. Such routine QI activities are rarely confused with research.

At the opposite pole from routine QI are efforts to develop and test new methods for improving health care quality. The latter constitute *QI research* and have as a *primary* goal producing generalizable knowledge that rests on accepted scientifically valid inferences or on qualitative research conducted according to recognized methodologies. The greatest problems arise in separating the middle category, *non-routine QI*, from the other two. Such activities include those that are explicitly designed both to improve care locally and to contribute to knowledge more generally (for example, by implementation at multiple health care organizations), or that affect care in ways that may confer additional risks (e.g., because of the interventions being used or the sharing of data).

Of course, ethical considerations apply regardless of whether a particular activity is considered routine QI, non-routine QI or QI research. Four principles are commonly articulated as underpinning ethical health care: respect for autonomy, beneficence, non-maleficence, and justice.[9,3,10] In addition, a moral argument can be made that activities should be designed to maximize learning (for society) for a given level of burden or risk.[3] Oversight to ensure adherence to these ethical principles can differ according to the type of activity: research with human subjects is federally regulated in the United States and typically requires oversight by an Institutional Review Board (IRB),[11] while mechanisms and policies for QI oversight vary across health systems.[12,13] Because of the rise in pragmatic trials that test system-level interventions, as well as the increasing sophistication of some QI activities, it is important to revisit the ethics and regulatory issues for these activities. In particular, in this article we seek to address two questions:

1. What policies surrounding oversight of QI, routine and non-routine, will help ensure adherence to fundamental ethical principles of health care?
2. Are there special considerations in the oversight of QI research activities that optimally protect patients and other participants yet allow for rapid system learning?

Differentiating types of QI-related activities

Routine, non-routine, and QI research projects, as defined above, must first be differentiated so that appropriate ethical and regulatory oversight can be applied. Subjecting QI activities to oversight by an IRB can unnecessarily impede local changes in practice aimed at improving care. Conversely, if research activities are erroneously labeled QI, they may escape required IRB oversight. Furthermore, if project leaders design a QI activity with inadequate rigor or measurement in order to avoid having it categorized as "research" so that it is not subject to IRB oversight, it may detract from the quality and usability of the data for any purpose.[3,10]

We believe that routine QI activities can be recognized as such by local clinical program leaders, without prior independent review of each project. Institutions should have written policies that delineate the bounds of routine QI so that local leaders can initiate and conduct projects using oversight mechanisms for clinical operations that are already in place. Policies should include the methods of intervention, measurement, and differential implementation (e.g., cluster randomization of or delayed implementation for some clinical units) that are acceptable within an institution without independent review.

For activities that do not clearly fit within the scope of routine QI, institutions need a process and criteria that allow independent determination of whether an activity should be considered non-routine QI or QI research. Ogrinc et al. have published a framework to differentiate research from QI that considers a project's intent and methods,[12] and other institutions have developed similar schemas. The Alberta Research Ethics Community Consensus Initiative (ARECCI) suggests that projects be screened to determine whether ethics review is needed, according to the purpose (create generalizable knowledge vs. other) and the level of risk.[14] Given the great degree of variability in the nature of these activities, a single criterion will never distinguish non-routine QI from research trials of care delivery alternatives, nor will a simple "checklist" reliably differentiate them. Instead, discussion and consideration of a number of attributes (Table 1) by those not directly involved in the project may help make this distinction project by project. An example of the continuum of QI activities—routine single-site QI, non-routine QI with concurrent comparison, and randomized research—is presented in Table 2.

Oversight of routine QI

It is beyond the scope of this article to suggest what constitutes a sufficient or optimal institutional strategy for routine QI as part of health care operations. However, in general, mechanisms in place for oversight of clinical care should suffice for routine QI activities related to that care. Of course, all such activities must be conducted in compliance with governmental regulations for clinical care and use of patient data (HIPAA),[15] as well as professional standards. Survey data from hospital executives indicate that important ethical considerations for the conduct of QI include exposing subjects (i.e., patients, health care providers, systems) to no more than minimal risk, focus on assessment and implementation of established practices, and respect for the privacy and confidentiality of subjects.[16]

While the details of reporting and oversight of clinical operations varies, clinical program leaders are responsible to institutional officials and, often, a Board of Trustees or Directors, for the provision of high quality, ethical clinical care. Even though prior independent ethics review of each project is generally not necessary, institutional policies and ongoing activities should be routinely reviewed by organizational leaders (often at a departmental level or by a quality and safety department). For transparency, health care organizations may wish to disclose, through a general notification to all patients when they enter the system, the existence and breadth of routine QI. Patient advisory councils are one way of obtaining local input and guidance on routine QI activities from the consumers of health care services. The considerations for separate oversight and review below are not intended to apply to these generally accepted activities.

Oversight of non-routine QI

Projects determined to be non-routine QI need independent oversight (though not necessarily by an IRB), to address specific aspects of design, potential risks to patients and clinicians, and need for disclosure about the activities. QI projects frequently use concurrent comparison groups (e.g., implementing a change on one ward and comparing to continuing current practice on another). For example, in QI learning collaboratives[17,18] multiple sites are involved in activities consistent with routine QI, but they also pool their data in order to answer broader questions about implementation. Whether assignment of units is done by willingness to participate, staggered implementation, or by random assignment does not, by itself, make the activity research. However, projects that implement QI interventions concurrently in multiple institutions constitute non-routine QI and independent review is warranted.

The body that oversees non-routine QI within an institution has a critical role in determining appropriate disclosure to various stakeholders. For example, while data privacy is covered under HIPAA, there may be cases of non-routine QI in which additional specific disclosure to those affected, including patients, clinicians, and other staff is warranted. Even in the context of research, there is controversy about whether assignment, particularly random assignment, of patients to a treatment requires different disclosure of risks than if it was chosen by a clinician.[4,19] Random assignment raises analogous questions for QI. We will not settle the current controversy about whether the mere fact of randomization should trigger a requirement for notification or consent.[3,20] However, we believe strongly that in such projects (QI or research) the need for notification or consent should be determined by a group that is independent from those conducting the project.

Non-routine QI activities will frequently be of interest beyond the involved institutions and this should be encouraged. The Office for Human Research Protections (OHRP) correctly states “intent to publish is an insufficient criterion for determining whether a QI activity involves research.”[21] Health systems may learn from one another's QI activities, even if the results would not be robust enough to answer a specific research question; and guidelines exist for publication of QI activities.[22] The existence of specialized ethical oversight for non-routine QI activities may satisfy those journals that require all work published in their

pages to have received IRB approval, thus enabling dissemination of important QI results to interested audiences.

The considerations in Table 1 illustrates that the distinction between non-routine QI and research is fluid and imprecise, and depends on the topic as well as on the nature of the intervention and measurement. We believe that organizational policies, which we outline as "recommendations" below, can allow for this fluidity, achieve both transparency and consistency in review and oversight, and promote maximal learning from proposed activities, regardless of the category to which they are assigned.

Are there special considerations in the oversight of QI research activities that optimally protect patients and other participants yet allow for rapid system learning?

There are many recent and current examples of research projects that are primarily designed to test specific hypotheses, but have elements of QI. The Central Line-Associated Bloodstream Infection (CLABSI) Study [23] involved the implementation of a checklist of five strategies to prevent catheter-related bloodstream infections in more than 103 ICUs. The Johns Hopkins (JHU) IRB determined the study was "exempt" but OHRP later determined that the JHU IRB erred by not classifying the activity as research and requiring IRB approval at each participating hospital.[24–26] However, OHRP did opine that waiving of consent was permissible. Several years later, in considering a project implementing the same intervention in a larger group of hospitals, OHRP determined that the intervention now represented the standard of care. While they mandated IRB approval at the coordinating site, they did not require it at each participating hospital.[24] The Randomized Evaluation of Decolonization versus Universal Clearance to Eliminate MRSA (REDUCE MRSA) trial[27] compared three strategies in current use for preventing methicillin-resistant *Staphylococcus aureus* (MRSA) infections in adult intensive care units (ICUs) of a single health system. In this case, a waiver of informed consent was granted, although the IRB required that patients be informed of the study through notices posted in each ICU room. As a final example, planning for the Improving Chronic Disease Management with Pieces (ICD-Pieces)[28] trial is now underway. ICD-Pieces is a novel information technology that leverages information from electronic health records (EHR) to identify patients with chronic kidney disease, diabetes and hypertension and provides clinician support to implement therapies and monitor outcomes. The research question is whether incorporating new information technology can facilitate collaboration among primary and specialty care providers. The investigators and groups overseeing the study concluded that there would be value in informing patients that their care providers will be notified about relevant EHR data but that no consent is required.

These three projects are all designed to answer questions about effectiveness of a system-level intervention, and some may turn out to improve the quality of care at participating institutions. Knowledge generated from these studies is qualitatively different than that which can be derived from typical QI projects. They are conducted in a large enough number of settings and with sufficient scientific rigor that generalizable knowledge

regarding the impact of the intervention should result. While the methods used cannot completely eliminate the effect of local context, they provide data on the average results across many contexts, as well as on the attributes of systems in which the interventions are more or less effective.

Ethical oversight of QI research needs to take account of the characteristics that distinguish it from other types of research. Research involving system-level change—such as a study of strategies to encourage clinicians to prescribe a medicine that has been previously proven to be superior—can affect patient outcomes, but it differs from research comparing two biologically active substances to treat an illness. Studies of the former sort align with quality improvement goals at each institution, and generally have minimal risk to patients. Conclusions about the average effect of the intervention across settings as well as in particular subgroups or contexts are possible, but it does not provide data on which clinical treatment is best. In conventional clinical trials, the treatment received is determined by the protocol, rather than the judgment of the clinician. In system-level interventions, typical of QI research, clinicians (as well as patients) are subjects of the research; while the intervention being studied (e.g., introduction of a guideline) may encourage the clinicians to recommend treatments, the choice still depends on clinician judgment and patient preference. The oversight process can take into account factors such as how directive the system-level intervention is in determining the appropriate level of disclosure to, and consent by, clinicians and patients.

Recommendations: Approaches to Oversight

In this section we make specific recommendations for oversight of routine QI, non-routine QI, and QI research. As a group, we represent multiple stakeholder viewpoints and have attempted to weigh ethical considerations for individuals with the benefits of more efficient learning activities of all kinds in health care; however, we represent no particular professional or regulatory body. While we hope these recommendations stimulate consideration about what is appropriate from an ethical perspective, project leaders and institutions are obliged to comply with current regulations of oversight agencies (e.g., CMS, OHRP, FDA and the Joint Commission).

Recommendation 1: Health care organizations should have systematic, transparent policies and processes for designating activities as routine QI, non-routine QI, or QI research and providing appropriate oversight for each

Clear written policies should exist to define the boundaries of routine QI that can be reasonably overseen by clinical program leaders within an organization, in consultation, as needed, with QI experts. Projects that are non-routine, because of their scope, design, or possible risks, should be reviewed by an independent individual or group with knowledge of privacy regulations, local QI oversight requirements, and research oversight to distinguish non-routine QI activities from research. This could be done by an experienced member of an IRB or another individual or group and may not require a full committee review. The considerations in Table 1 may be helpful in making the distinction between QI, non- routine QI and QI research for purposes of oversight. Development of policies that separate routine activities from non-routine projects should be informed by stakeholder views. The scope of

routine activities should be discussed with patient advisory groups through existing processes that allow input on operations in health care organizations.

Recommendation 2: Health care organizations should have formal and independent oversight of non-routine QI activities

Of course, ethical and privacy issues exist in routine QI, as they do in clinical care; risks must be minimized, HIPAA and other regulations apply, and attention to engagement of patients and other stakeholders is critical. As noted above, oversight mechanisms for clinical operations should be sufficient for routine QI. These issues, however, are likely to be more significant or complex in non-routine QI projects and require more formal, independent oversight. Instead of an IRB, oversight of non-routine QI projects could be under the aegis of a body specifically constituted for this task. Such a group could include QI experts (e.g., from a hospital's department of quality and safety), health services researchers, administrators, clinicians, patient representatives, and those experienced in ethical review of health care activities. This process would also serve to internally “register” non-routine QI activities with the institution, and to encourage reporting of results, both positive and negative. The key is that the oversight be consistent, transparent, credible, and include individuals not directly involved in the activity. The value and opportunity costs to the system and its future patients may be considered in conjunction with the benefits and risks to those that the project will immediately affect. Specific requirements for patient (or other stakeholder) notification and even consent may be deemed appropriate for particular projects. Whether under the auspices of an IRB or a separate body, review and oversight should be tailored to QI projects, and not be bound by external or internal research oversight requirements.

Recommendation 3: QI research should be reviewed by an IRB; for such review to be effective, IRB's should develop particular expertise in assessing QI studies

Research related to QI requires IRB review. This review will determine what disclosure, consent and authorization is necessary for each research project based on the standard requirements in federal regulations on human subject research. Those regulations take account of many factors including the level of risk to patients, providers, and systems. While evaluating risks to patients is important, it may be equally important to consider potential benefits and burdens that may accrue directly to all the stakeholders. (See *Harms, Benefits, and the Nature of Interventions in Pragmatic Clinical Trials*[29] in this series of papers for more on this broader approach.) Just as some IRBs use subcommittees to review behavioral studies or survey research, institutions whose staff conduct QI research should make sure that the IRB possesses the necessary expertise to assess commonly encountered scenarios in QI research. For example, when researchers obtain data from a number of health care institutions where an intervention is implemented for local improvement purposes, it might be appropriate for the project to receive IRB approval only at the institution where the researcher is based, while the participating institutions provide whatever oversight they usually apply to locally focused QI activities. Patients and clinicians should, however, be notified in culturally and linguistically appropriate ways that QI data from their site are being used in a research study being conducted by another institution.

Recommendation 4: Stakeholders should be engaged in the review of non-routine QI and QI research

Stakeholders in health care research and QI activities include patients, clinicians, administrators, staff and others, with impact on any particular group varying with the activity under consideration. We recommend including stakeholders at all stages of non-routine QI and QI research development, approval and implementation, as well as attending to methods of notifying stakeholders about QI activities at the institution. Those with institutional responsibility for these activities should actively seek the opinions of relevant stakeholders to better understand their interests and priorities. (See *Gatekeepers for Pragmatic Clinical Trials*[30] in this series of papers for more.)

For non-routine QI projects and QI research, the degree of engagement could depend on the potential impact of the proposal on each stakeholder group. Clear roles and responsibilities for patients and others will help ensure that stakeholder involvement is meaningful.[31] At a minimum, stakeholders of any health system should have access to information regarding the types of non-routine QI and QI research activities that are undertaken, and the criteria that will be used to determine when patients will be individually notified and specific consent required. A site-specific comprehensive registry of local ongoing QI activities, accessible to the public, may be the most expedient notification method, and deserves further discussion. Transparency and communication are essential, and print and electronic media should be consistently used for communication to patients about non-routine QI and QI research activities. Disclosing information about these activities manifests respect for stakeholders and can encourage them to become more fully engaged as collaborators in optimizing health care systems.

Conclusions

The increasing use of pragmatic research in routine care settings, juxtaposed with increasingly extensive and sophisticated QI activities, has made the boundary between QI and research less distinct. However, at their respective cores, QI is designed to change local processes to reliably achieve accepted standards of care while pragmatic research is designed to determine the standards themselves. Both sets of activities should be common in all organizations that aspire to be learning health systems,[32] and both require oversight. Routine QI projects may be supervised by local leaders already charged with oversight of quality of clinical care and other operations, but the bounds of “routine” should be made explicit within organizations. Projects that could result in substantial changes to care and/or include the possibility of additional risks and burdens to patients should have independent review to assess if they are research or QI. In either case, such projects should receive appropriate institutional oversight by an independent individual or a multi-stakeholder panel with relevant expertise. The goal of this review and oversight is not to place additional hurdles in front of learning how to safely and reliably deliver the best care to patients. Rather, it is to make these non-routine activities more relevant (from the perspective of patients and clinicians), robust (designed to optimize learning for a given level of risk or burden), and transparent to all.

The current mechanisms of research review and oversight have served the public well by protecting patients who participate. But those mechanisms sometimes force research on system-level changes in care delivery into paradigms better suited to hypothesis testing about biologically active treatments. What we seek is a system that more systematically and efficiently assesses and oversees both QI activities and research. By expanding oversight of QI projects that have potential risks or burdens, we seek to raise their level of rigor and eliminate the perverse incentives to use weaker designs to avoid triggering IRB review. The kind of oversight we envision will bring patients and other stakeholders actively into the QI and research activities of their health care institutions, allowing them to help set priorities about the topics of learning activities and the methods by which they are conducted. Only by doing so will we facilitate both research in health care delivery and learning through QI methods as two important and complementary activities of a learning health system.

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Table 1

Factors to consider when assessing and classifying QI and Research activities

Factor	The proposed activity is probably routine QI when...	The proposed activity is probably non-routine QI when.	The proposed activity is probably QI research when.
Purpose of the activity	Primary intent is to improve care in a local clinical delivery system. Results are intended to be locally implemented immediately. May be shared as a QI report	Often seeks to improve care in multiple systems, or may have more inherent risks than routine QI. Leaders often intend to share results broadly. May be part of a related research initiative.	Tests a particular hypothesis or answers an articulated study question in a way that is primarily intended to produce generalizable knowledge. May also be designed to improve care locally.
Project leadership and sponsorship	Leaders are from within the clinical unit or system. Sponsorship usually within an institution.	Leaders are often from one of the clinical units or systems. Sponsorship may be external or from within an institution.	Leaders and sponsorship commonly are external to the clinical unit under study.
Locus of intervention/randomization	Typically changes a process at the level of a clinical system, applied to all patients.	Typically changes a process at the level of clinical systems. May sometimes randomize clusters within or among clinical systems.	May be applied to some individuals and not others. Random assignment at the level of the individual is common
Locus of clinical decisions	Clinical decisions are made by individual clinicians and patients, though may be influenced by standardized processes, guidelines or other methods	Clinical decisions are made by individual clinicians and patients, though may be influenced by standardized processes, guidelines or other methods, which may vary among participating units.	Adherence to study protocol determines treatment, though protocols in pragmatic trials may be more flexible than classical randomized controlled trials
Ability of individuals to opt out of intervention	Difficult for individuals to opt out of local system-level interventions	Difficult for individuals to opt out of local system-level interventions.	Typically voluntary. Informed consent may be required or waived by a reviewing IRB
Data analysis/monitoring	Collection of data associated with minimal burden on patients. Typically uses displays of data over time, statistical process control and related QI methods. If evidence emerges that performance is negatively affected, the intervention is immediately stopped.	May have additional patient burden for measurement. Analysis primarily uses QI methods, but may use other analytic techniques to assess effects across participating systems.	Patient burden for data collection may be substantial, though pragmatic trials may also be integrated into ongoing care processes. May use statistical analysis of data at specified points to test stated hypothesis. Data and safety monitoring plans may be required.
Dissemination of study results	Findings are implemented immediately within the participating organization(s) and in other venues for shared QI initiatives. May sometimes be published as a QI report.	Findings are disseminated within the participating organization(s) and in other venues for sharing QI initiatives, but more likely to be more broadly disseminated at professional meetings and through publication.	Dissemination is an expectation of research results through research meetings and peer-reviewed journals.
Application of Findings / Expected Actions	Improvements are immediately implemented in care processes locally. An expectation exists for continuing tests of change and measurement.	Improvements are immediately implemented in care processes. Typically adopted (with adaptation) by other organizations.	Typically delayed translation of findings to clinical care. However, the expectation of pragmatic trials is for more immediate dissemination and implementation.
Accountability and regulation	Oversight is by clinical and institutional leadership under specific policies for routine QI activities. HIPAA and other regulatory rules apply.	Oversight should be by a qualified group within an institution in addition to usual clinical leadership. HIPAA and other regulatory rules apply. Specific requirements for patient notification or consent may be deemed appropriate.	Institutional oversight is through an IRB, which operates within federal regulations including the Common Rule and HIPAA.

Factor	The proposed activity is probably routine QI when...	The proposed activity is probably non-routine QI when.	The proposed activity is probably QI research when.
Stakeholder Engagement	Input of patient representatives is through institutional channels for patient input in clinical care.	Patient input should be sought for prioritization and conduct of major QI activities.	Patient-centered research should include patients as partners in prioritization, conduct, analysis, and reporting.

Table 2

To demonstrate the continuum of learning activities and recommended oversight, consent, and stakeholder engagement, we consider the following hypothetical example: Evidence suggests that rapid cardiac catheterization with coronary reperfusion after myocardial infarction (MI) improves outcomes. A multidisciplinary workgroup in an institution is convened to decrease the time from ST-elevation MI (STEMI) to angioplasty ("door to balloon time" [D2BT]). The group decides to test the impact of paging the interventional cardiologist when emergency medical technicians notify the hospital that they are en route with a patient with possible MI. This has been reported to be a successful approach in similar hospitals. This is a *change* in process, because currently the cardiologist is notified only after the diagnosis of STEMI is confirmed in the emergency department (ED). Several approaches are possible, as shown below.

	Design	Measures	Designation of Activity*	Causal Inference	Recommendations: Oversight, Consent, and Stakeholder Engagement
0.	Usual care: Cardiologist is notified after patient arrives in ED and STEMI diagnosis is confirmed.	Mortality and D2BT are routinely tracked	Current local practice	N/A	Routine oversight and regulation of clinical care
1.	PDSA cycle in 1 ED: Implement change in a single institution (EMT's page cardiologist while en route).	Change in D2BT and mortality charted using statistical process control methods to determine if changes are unlikely to be due to chance.	Routine, local QI. The activity is **not** a systematic activity designed to contribute to generalizable knowledge; but, rather, seeks to make and monitor the impact of a local change.	Ability to make causal inference is limited: if a decrease in D2BT is seen, it is possible that another factor actually caused the reduction in D2BT.	This routine QI project should be undertaken with oversight of clinical leaders of the unit involved, but should not require independent review. Patients of the institution should be made aware that routine changes in care with measurement are commonly undertaken.
2.	Improvement cycles with comparison: 2 EDs assigned or randomized to intervention or to usual care.	Above plus: Observations about differences in the EDs (census, staffing)	Local QI. This is also **not** a systematic investigation. In addition, the change is low risk and easily reversible (in case of unexpected harm).	Causal inference is still limited. The activity may help generate hypotheses to be tested in research.	As this becomes a system-wide initiative, stakeholder engagement may be appropriate to insure that health system leaders are aware, patients are engaged as appropriate, and to maximize local learning. Oversight by a body specifically convened for QI activities may be appropriate.
3.	20 ED's convene to improve D2BT. Units choose whether to implement a change, or may have a menu of possible changes.	Above plus: The group might analyze the attributes of institutions in which the interventions appeared to have the greatest effect.	Non-routine QI (QI Collaborative). This is not a systematic investigation. The intervention is strongly mediated by the judgment of each health system rather than assignment by the project leaders or by chance.	Sharing of aggregate data may lead to provisional learning and hypotheses to be tested in research. There may be more useful learning in the aggregation of experience, but causal inference from a scientific perspective is still limited.	Given the extent of the project, review should be required to confirm that this meets criteria for QI. Oversight as QI might include QI experts, health services researchers, administrators, clinicians, patient representatives, and those experienced in ethical review. Because data (even aggregate) will be shared, and the activity is part of a larger initiative to improve care for patients with STEMI, stakeholder engagement and communication is warranted.
4.	20 EDs, cluster-randomized to change or no change	D2BT, mortality, potential patient-level confounders. Quantitative analysis accounts for clustering of observations within sites.	Multi-center research. The activity is designed to determine (with statistical certainty) the average effect of the change, and to create generalizable knowledge.	Causal inference: Alerting the cardiologist from the ambulance is (or is not) related to both D2BT and health outcomes.	The activity in the intervention sites looks identical (from the patient's perspective) to the QI activities described above. While IRB approval is required, they may decide that the requirement for informed consent of individual patients can be waived, since the intervention is low-risk, and consent would be impractical to obtain. Patients of the health system should be notified that the research is underway. Policies should exist that assure immediate

Design	Measures	Designation of Activity*	Causal Inference	Recommendations: Oversight, Consent, and Stakeholder Engagement
				implementation at all sites if improvements in outcomes are documented.
				implementation at all sites if improvements in outcomes are documented.

Abbreviations: MI, myocardial infarction; ED, emergency department; D2BT, door to balloon time; QI, quality improvement; CFR, Code of Federal Regulations.

*With the exception of routine QI, more extensive projects should be reviewed first to distinguish QI activities from research, and to determine appropriate oversight. This corresponds with recommendation 1: Health care organizations should have systematic transparent processes for designating activities as routine QI, non-routine QI, or QI research and determining what independent evaluation each will receive.